Attorney Docket No. MP/143

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Walter
Appl. No. : 09/369,231
Filed : August 5, 1999
Title : Surface Modified Expanded Polytetrafluoroethylene Devices and Methods of Producing the Same

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office on January 23, 2004.

Melanee Williams
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Group Art Unit: 1771
Examiner : H. Vo

Commissioner for Patents
P.O. Box 1450
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SUPPLEMENTAL DECLARATION OF JAMES T. WALTER

1. My name is James T. Walter and I am the named inventor in the above application. I provide this Supplemental Declaration to clarify information supplied in my Declaration of June 6, 2003, and to provide additional information in support of the patenting of the present invention.

2. In my Declaration of June 6, 2003, I explained that the material produced in accordance with the present invention is completely novel over all previous polytetrafluoroethylene (PTFE) materials. That is, the structure defined by the claims in the present application has never existed in the art prior to the present invention.

3. In particular, the present invention provides an expanded PTFE structure that is totally new in at least three respects:

First, the present invention defines a material having "a surface comprising expanded PTFE having a node and fibril microstructure; the surface having a number of node clusters, said node clusters comprising multiple nodes interconnected by fibrils, and gnarled nodes situated between the node clusters; and said gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length."

Second, the present invention defines a material having "a surface comprising expanded PTFE having a node and fibril microstructure; said surface comprising a textured pattern having multiple ridges and valley surfaces, the ridges comprised of node clusters; said node clusters comprising multiple nodes interconnected by fibrils; the valley surfaces

having gnarled nodes protruding th refrom; and said gnarled nodes having a protruding length and b ing substantially devoid of fibrils along th protruding length."

Third, the present invention defines a material having "expanded PTFE having a node and fibril microstructure; at least one node having a protruding length measured from a valley surface, the at least one node being substantially devoid of fibrils along its protruding length; the at least one node being adjacent to a ridge having a height; and the protruding length of the node being greater than the height of the adjacent ridge."

In case there was any ambiguity in my prior Declaration, in at least these three respects the claims of the present application define a structure of ePTFE that to my knowledge has never existed prior to the present invention. In other words, the present invention defines an ePTFE structure that was not previously taught or suggested by anyone.

4. Contrary to the position taken by the Patent and Trademark Office, the cited reference to Okita et al. (United States Patent 4,734,112) does not teach or suggest a material in accordance with the claims of the present application. Further, there is nothing in the Okita et al. patent that in any way suggests such a structure. It is asserted in the present Office Action that "It appears that both Okita and Applicant is [sic] using the same laser treatment to modify the surface of the ePTFE, it is not seen that the ePTFE of Okita would have possessed a surface structure different from Applicant's material." Office Action of July 25, 2003, at page 3. This conclusion is not true. In my previous Declaration I explained that the Okita et al. patent does not teach the surface structure of the present invention. Further, I demonstrated in detail that such a structure was not inherent in the teachings of the Okita et al. patent since that patent teaches a completely different method of surface treatment that will not yield the structure defined in the claims of the present application.

5. The Okita et al. patent teaches a surface structure that is very distinct from the structure of the present invention as claimed. There is nothing in the Okita et al. patent that in any way teaches or suggests a surface structure similar to the present invention as claimed.

6. Starting around 1995 W. L. Gore & Associates, Inc. ("Gore"), assignee of the present invention, commercially launched a surgical sheet product for treating hernias under the trademark DUALMESH®. This product comprised a patch having a smooth top surface and a smooth bottom surface, with the top surface microscopically structured to prevent tissue in-growth and the bottom surface microscopically structured to encourage tissue in-growth. This product was technically and commercially successful; by 1999 the product was experiencing steady but not dramatic annual sales growth. In Octob r 1999 W. L. Gore & Associates, Inc., introduced a modified

DUALMESH® product that included an in-growth surface that includ d a macroscopically roughen d structure in accordanc with the pres nt invention. This product continued to be marketed under the DUALMESH® trademark with an added secondary trademark CORDUROY®. This DUALMESH® CORDUROY® product included a smooth exclusionary top surface and a macroscopically rough in-growth bottom surface that included a repeating textured pattern of gnarled nodes situated between the node clusters, the gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length. This commercial product was shown and described at the interview held on May 29, 2003.

7. From its introduction in October 1999 to date, this DUALMESH® CORDUROY® product has experienced significant commercial success. Upon information and belief, the introduction of the improved product made in accordance with the present invention is currently contributing over $1,000,000 per month in additional revenue for Gore over the predecessor DUALMESH® product; since introduction in 1999, this has contributed well in excess of $20,000,000 additional revenues that Gore would not have achieved if it had continued to sell only its original DUALMESH® product. While some other factors may have contributed to some of this increase in sales, upon information and belief, a major portion of this commercial success has been a direct result of the structural properties provided to the improved product by the present invention.

8. The DUALMESH® CORDUROY® product made in accordance in the present invention has also been enthusiastically accepted by clinicians. For example, in the article "Tissue attachment strength of prosthetic meshes used in ventral and incisional hernia repair," Surg. Endosc. (2002) 16:1542-1546, copy attached, it is reported that the improved product of the present invention ("DLMC") provides significantly better tissue in-growth than Gore's original DUALMESH® product as well as providing as strong or stronger tissue attachment as competitive polypropylene mesh products. With this improved tissue attachment, the researcher suggests that the DUALMESH® CORDUROY® product of the present invention should be the material of choice over both the original DUALMESH® product and polypropylene competitive products.

I hereby declare that all statements made herein of my own knowledge are true and that the statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 1-22-04

James T. Walter

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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Tissue attachment strength of prosthetic meshes used in ventral and incisional hernia repair

A study in the New Zealand White rabbit adhesion model

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Abstract
Background: Many prosthetic materials are used in incisional hernia repair, including polypropylene (PP) and expanded polytetrafluoroethylene (ePTFE). However, PP forms severe adhesions and ePTFE has raised concerns about the adequacy of tissue attachment.
Methods: The early tissue attachment strength of PP and two new forms of ePTFE (DLM and DLMC) was compared in a rabbit model ($n = 12$) in which disks of the three meshes ($n = 8$ of each material) were implanted against the abdominal wall for 3 days.
Results: Tensiometer testing found that DLMC mesh had significantly greater attachment strength than PP ($p = 0.02$). Histologic studies indicated that this was due to cellular ingrowth. Tissue adhesions were observed with all eight PP disks, one DLMC disk, and none of the DLM disks.
Conclusion: Modified forms of ePTFE mesh may provide abdominal wall repairs that are as strong or stronger than those obtained with PP, with early tissue attachment and without adhesions.

Key words: Hernia — Ventral hernia repair — Incisional hernia repair — Polypropylene — Polytetrafluoroethylene — Rabbits — Adhesions

Several prosthetic materials have been used in ventral and incisional hernia repairs, especially laparoscopic procedures, to reinforce the repair without creating tension. Currently, polypropylene (PP) and expanded polytetrafluoroethylene (ePTFE) meshes are the most commonly employed, although their physical characteristics are considerably different. Meshes composed of PP are relatively stiff and screenlike, with large holes. They have been found to provide a strong clinical repair [9, 18], but they also elicit an intense inflammatory tissue response [5, 11, 17] that may lead to severe adhesions, erosion, or fistulization [15]. On the other hand, ePTFE meshes are soft and pliable, with microporous interstices that allow good tissue ingrowth while evoking minimal inflammation and adhesion formation [3, 11, 12] and apparently providing some resistance to infection [5]. However, because of the relatively smooth surface of traditional ePTFE meshes and the lack of a strong inflammatory response to them, some researchers have expressed concern about the strength of the attachment of tissues to these prostheses and hence the strength of clinical repairs in which they are used [4].

In response to this concern, modified forms of ePTFE mesh have been developed. One is a dual-surface mesh (Gore-Tex DualMesh Biomaterial [DLM]; WL Gore & Associates, Flagstaff, AZ, USA), which has a smooth side that is placed adjacent to the viscera to minimize adhesions and a rougher side that is placed against the abdominal wall to encourage tissue attachment. This type of mesh was recently further modified (Gore-Tex DualMesh Biomaterial with Corduroy Surface [DLMC] so that the rough surface has irregular ridges, which theoretically should increase tissue attachment by providing a microabrasive surface. Whether this modification actually increases the strength of tissue attachment has not previously been investigated in either experimental or clinical studies. Therefore, we conducted a laboratory study to compare the tissue attachment strength of PP, DLM, and DLMC in a rabbit model.

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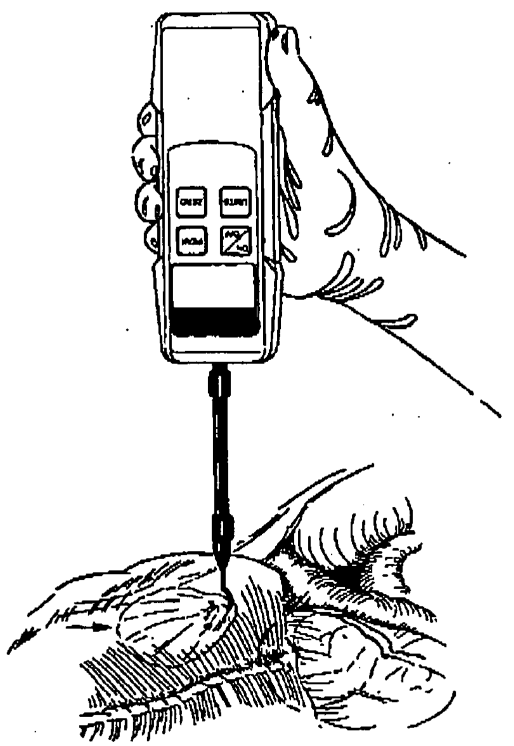


Fig. 1. Tensiometer test used to measure tissue attachment strength of prosthetic meshes after implantation in rabbits for 3 days. Arrow indicates mesh against the peritoneal wall. Sutures placed around the mesh at implantation have been removed.

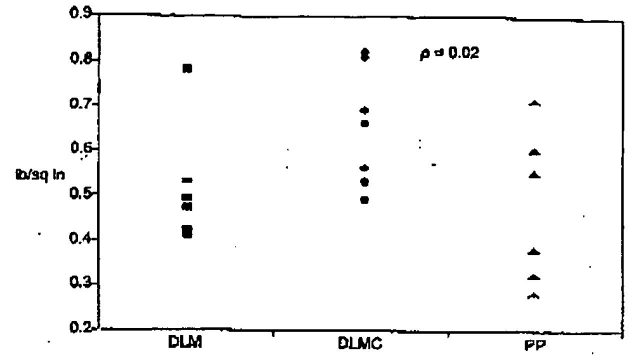


Fig. 2. Graph showing results of tensiometer test of tissue attachment strength of all 20 samples of the three types of mesh assessed $n = 6$ for DualMesh [DLM], $n = 7$ for DualMesh with Corduroy Surface [DLMC], and $n = 7$ for polypropylene [PP]. The difference between results with DLMC and those with PP was significant ($p = 0.02$); other comparisons did not yield significantly different results.

Methods

Twelve New Zealand White rabbits (2–3 kg) were cared for and used in the study in accordance with the National Research Council Guide for the Care and Use of Laboratory Animals guidelines. In each animal, two disks (3.8-cm) of either DLM, DLMC, or PP mesh were implanted intraabdominally against the peritoneal wall (one on the right side and one on the left) in contact with the viscera. The implantation sites and mesh types used in each animal were selected in accordance with a rotation design that resulted in a total of eight implantations of each mesh material. With this implant design, each rabbit received only two of the three mesh types. Overall, however, each mesh was implanted a total of four times. In other words, the rotation pattern alternated DLM/DLMC, DLM/PP, or DLMC/PP, with one of each pair implanted on either side of the linea alba per individual animal.

For the implantation procedure, the rabbits was anesthetized and placed in a dorsal recumbent position. In a ventral midline approach, an incision of 10–15 cm was made over the linea alba between the xiphoid process and the pubic symphysis. A mesh disk was then implanted against the peritoneal surface of the anterior abdominal wall 2–4 cm to the right of the linea alba, at the level of the umbilicus. A second disk composed of a different type of mesh was placed in the same location contralaterally. All disks were secured with continuous sutures of CV-4 Gore-Tex® suture. After implantation, the peritoneum and linea alba were closed with interrupted sutures, the subcutaneous layer was sutured by using either an interrupted or a continuous pattern, and the skin was closed with surgical staples.

Postoperative care of the rabbits included administration of an analgesic (butorphanol), if necessary. No antibiotics were given to any rabbit. All rabbits recovered from surgery uneventfully. Three days after the implantation procedure, the animals were killed by intravenous administration of a barbiturate overdose. The implantation sites were exposed, and any adhesions observed between the implanted mesh and tissues were graded for extent (with 0 indicating that no adhesions were present; 1 indicating that 25% of the mesh disk was covered with adhesions; 2 that 50% was covered; 3, 75%; and 4, 100%) and tenacity (with 1 indicating flimsy adhesions; 2, adhesions requiring blunt dissection for separation; and 3, adhesions requiring sharp dissection for separation).

After the adhesion assessment, the sutures surrounding each mesh disk were cut. A hand-held tensiometer (DPS-11; Imada Co., Japan) was then attached to one edge of each disk (Fig. 1), and the disk was pulled out of the soft tissue. The peak force required to separate the entire disk from the soft tissue was recorded (tissue attachment strength).

Subsequently, the mesh disks and surrounding 2 cm of tissue were immersed in 10% neutral buffered formalin. Representative samples of each mesh were then prepared for histologic analysis. Five-micron paraffin sections were stained with hematoxylin and eosin to allow identification of cells and with Milligan's trichrome for identification of connective tissues.

The values for tissue attachment strength for the three types of mesh were compared statistically by using a balanced incomplete block design to remove animal-to-animal variation. A p value of < 0.05 was considered to represent statistical significance.

Results

For four mesh implants, tissue attachment strength could not be analyzed because of technical difficulties, including inadvertently retained sutures and tearing of tissue in areas other than the implantation sites. Therefore, six DLM, seven DLMC, and seven PP implants were available for this analysis. The mean force required to remove the implanted disk of mesh was 0.52 lb/sq in for DLM (range, 0.41–0.78), 0.66 lb/sq in for DLMC (range, 0.49–0.82), and 0.47 lb/sq in for PP (range, 0.28–0.71 lb/sq in). The differences in values for attachment strength between PP and DLM and between DLM and DLMC were not significant ($p = 0.06$), but significantly more force was required to remove the DLMC mesh disks from the tissue than to remove the PP disks ($p = 0.02$, with 95% of the eight confidence) (Fig. 2); thus, DLMC was found to have significantly greater attachment strength.

The adhesion assessment found no adhesions in 16 of the 24 explanted mesh disks, as follows: none of the eight DLM disks, seven of the eight DLMC disks, and

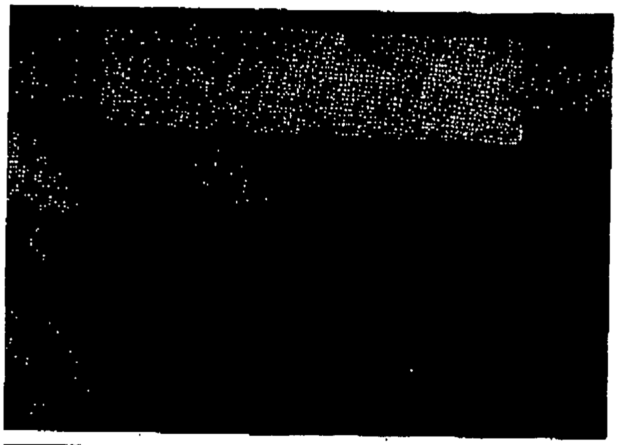
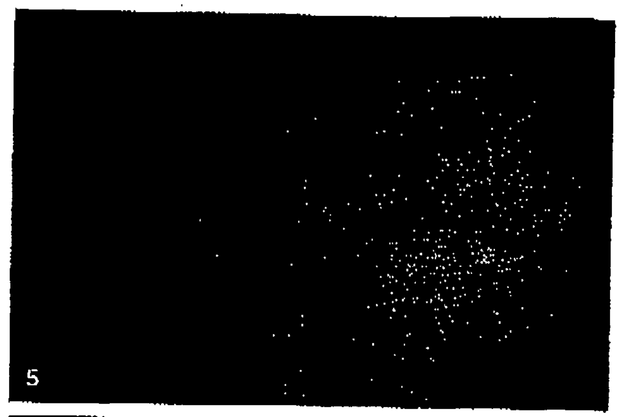


Fig. 3. Gross photo of the adhesions to the DLMC. The colonic adhesions also involved the linea alba and the contralateral PP mesh (*arrow*).

Fig. 4. Gross photo of the colonic adhesions to the PP mesh (*arrow*). This is a different implant than the one shown in Fig. 3.



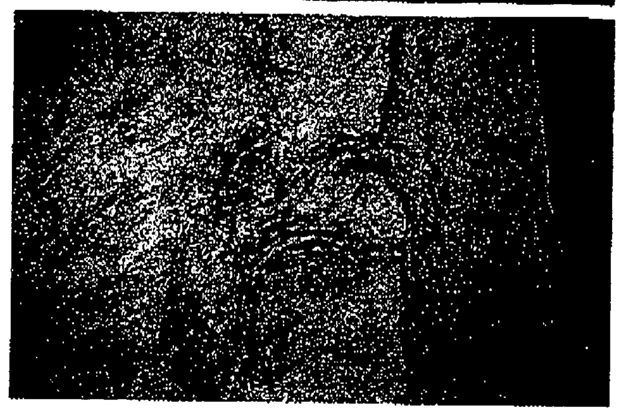


Fig. 5. Histologic analysis of representative sample of polypropylene (PP) mesh placed against the peritoneal wall in a rabbit for 3 days. The large vacuoles are the filaments of the mesh. Proteinaceous fluid is the predominant feature; a few white blood cells and erythrocytes are present, indicating no or minimal cellular ingrowth. Milligan's trichrome, original magnification ×10.

Fig. 6. Histologic analysis of representative sample of DLMC placed against the peritoneal wall in a rabbit for 3 days. Numerous neutrophils and histocytes appear in the interstices of the mesh (*arrow*). Milligan's trichrome, original magnification ×10.

one of the eight PP disks. The adhesions on the DLMC disk received a grade of 1 for extent and 1 for tenacity. In the only DLMC with adhesions, the colon was loosely adherent to the barrier surface of the biomaterial (Fig. 3). Five of the seven PP disks with adhesions received the same grades. Adhesions to the other two PP disks were more severe; the grades were 4 for extent and 1 for tenacity and 2 for extent and 1 for tenacity, respectively. The adhesions to the PP discs typically involved intestine and covered portions of the mesh as well as the suture line (Fig. 4).

Histologic studies of representative samples of each implant revealed that, in general, the PP mesh was surrounded by proteinaceous fluid (Fig. 5), with a lack of cells within the mesh, although a few neutrophils were observed at the tissue interface. For DLM, the periimplant membrane consisted of early granulation tissue, with cells (predominantly histocytes and neutrophils) stacked at the interface. Few cells were observed in th interstices of the material. For DLMC, the periimplant membrane also consisted of early granulation tissue. However, numerous cells, mainly histocytes and neutrophils, were present at the tissue interface and in the interstices of the mesh (Fig. 6).

Discussion

From previous laboratory experiments, we have found that significant tissue penetration will occur in prosthetic biomaterials within 7–14 days [12, 13]. The tested time period of 3 days was chosen to evaluate the early phase of cellular ingrowth and therefore tissue attachment in these materials. Based on this prior research, we assumed that in any subsequent time span the amount of ingrowth and collagen deposition will increase, thereby increasing tissue attachment strength. The literature on this correlation is quite sparse. This study is an effort to identify thes facts.

In this study in rabbits in which two types of ePTFE mesh (DLM and DLMC) and one PP mesh were implanted onto the ventral surface of the abdominal wall,

we found that, compared with PP, DLMC had a significantly stronger attachment to tissue on tensiometric assessment 3 days after implantation. There was no difference between PP and DLM.

Histologic studies showed marked cellular ingrowth at the tissue interface and in the interstices of the DLMC mesh after only 3 days, whereas the PP mesh was surrounded mainly by fluid, with few cells present. The cellular response in the DLMC was noted to be predominately histocytes and fibroblasts. Histocytes rid the healing wound of cellular debris, but more importantly these cells secrete fibroblastic growth factor, which stimulates angiogenesis and attracts fibroblasts. These fibroblasts, in turn, are responsible for collagen synthesis, which closes the wound and is responsible for the early strength of wound repair. Thus, the early greater attachment strength of DLMC compared with PP was apparently due to increased rapid cellular ingrowth, whereas the lesser attachment strength of PP probably resulted from the lack of cells and predominance of fluid at 3 days after implantation.

In other words, from the histologic evaluation of the tissue samples, it is clear that there was more tissue fluid and fewer cellular components in the healing process in the PP implants. It appears that the significantly irregular surface of the second-generation DualMesh (DLMC) provides more surface area for cellular attachment. This, in turn, provides the initiation of the release of more adhesion factors such as adhesions, fibrin, fibronectin, etc., which results in significantly earlier attachment to the tissues by the DLMC.

Concurrently with the attachment strength findings, minimal adhesions to the ePTFE mesh samples were observed; no DLM disk and only one DLMC disk showed any adhesions at all. In contrast, all but one of the eight PP samples showed adhesions, and two had adhesions sufficiently strong to require dissection for separation. Admittedly, this time frame of 3 days is rather short to evaluate adhesions in the experimental model. The extent and tenacity of adhesions declines over the next 90 postimplant days. However, the paucity of adhesions to DLM and DLMC at 3 days corresponds to the results of our prior studies, demonstraing that these biomaterials have a low incidence of adhesion formation subsequent to that time period [12, 13].

The tissue response characteristics of various PP and ePTFE meshes used for abdominal wall repair have been studied in many clinical and laboratory investigations. Most experimental studies have found that PP produces significantly more severe adhesions than ePTFE [3, 4, 11, 12, 14, 17]. These findings are supported by the current study. Because of clinical concern that adhesions may eventually result in bowel erosion, fistulization, or obstruction [18, 19], most surgeons do not use PP mesh in procedures in which a prosthesis is placed in an intraperitoneal location, as is done in laparoscopic [8, 13, 20, 21] and Rives-Stoppa open [1, 16] ventral and incisional hernia repairs.

Results of studies of tissue ingrowth int prosthetic meshes have been more variable, especially with respect to ePTFE. Some of the variability may be due to differences in the specific form of ePTFE assessed; thus, lack of tissue ingrowth was sometimes observed in experimental studies of an older, less porous form of ePTFE (Gore-Tex Soft Tissue Patch [STP]) [17]. However, other investigations of STP in animals found that collagen penetrated its interstices in a regular pattern and that mesothelial cells appeared in a continuous layer on the surface, thereby forming a neoperitoneum [11,12]. Moreover, some experimental studies of the STP form of ePTFE found — as we observed with DLM and DLMC in this study — that the strength of attachment at the prosthesis–tissue interface was at least as strong with ePTFE mesh as with PP ($p > 0.05$) [10]. Some of the discrepancies in results of tissue attachment studies of the various prostheses may have arisen due to differences in implantation techniques and sampling protocols.

Because of the variations in findings on tissue ingrowth, as well as the increasing clinical use of ePTFE prostheses in laparoscopic ventral and incisional herniorrhaphy, development of new types of ePTFE mesh has focused on further enhancing tissue incorporation while maintaining ePTFE's low propensity to form adhesions. DLM, the first type of ePTFE mesh with one smooth and one rougher surface, began to be used clinically in 1994 and has been employed extensively and successfully, with low rates of hernia recurrence, in several large clinical series [7, 8, 13, 20, 21]. In the experimental study described here, we found that DLM produced no adhesions and had both good cellular ingrowth by 3 days after implantation and an attachment strength equal to that of PP ($p = 0.06$ for the difference between results for DLM and PP on tensiometer testing). Previous experimental studies of DLM revealed that the prosthesis is well tolerated, has little tendency to form adhesions, and is a good substrate for gradual formation of homogenous and organized tissue; moreover, the tensile strength of the prosthesis–tissue interface increases with time [2].

Our study is the first to investigate DLMC mesh, a new form of DLM designed to provide an additional degree of tissue incorporation. Theoretically, the ridges on the surface of DLMC that is placed against the abdominal wall should enhance tissue ingrowth by providing microabrasive stimulation to the surrounding tissues. Additional studies of DLMC are needed, but our findings indicate that the ingrowth achieved with this new ePTFE mesh provides early tissue attachment strength that is significantly greater than that obtained with PP mesh, the pores of which were filled predominantly with fluid rather than cells after 3 days of implantation. Clinically, the rapid tissue incorporation with DLMC may help to mitigate recurrence of ventral and incisional hernias due to inadequate fixation of th mesh, a problem observed in many clinical trials [13, 20]. If strong, rapid tissue incorporation can be ensured, the mesh fixation technique that is used may become less important. It may even be possible to use absorbable sutures in laparoscopic repairs.

Recently, several composite meshes for abdominal wall repair have been described, including double-layer materials with one layer composed of PP and one of ePTFE [19] and PP meshes to which various anti-ad-

hesion substances have been applied [6]. As with all new meshes, including DLMC, the data on composite meshes are still limited and there are no reports on large randomized clinical trials. However, if a mesh made of ePTFE, which is generally accepted to have low adhesion potential, also provides strong, rapid tissue attachment, we see no reason to subject patients to the possible risks associated with inserting a mesh containing any PP into the abdomen.

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